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Tumor volume measurements vs diameter-based measurements (mRECIST) for response evaluation in pleural mesothelioma

Submission date	Recruitment status	[ ] Prospectively registered
31/12/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/01/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/01/2024	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pleural mesothelioma (PM) is an aggressive type of cancer that arises from the pleural mesothelium, a thin layer covering the lungs and chest wall. The aim of this study is to investigate whether using the tumour volume makes the response evaluation more reliable compared to the current mRECIST criteria (diameter-based measurements).

Who can participate?
Patients aged 18 years and over with pleural mesothelioma

What does the study involve?
All patients will be treated by their own treating physician. However, during this study, an additional response evaluation based on tumor volume will be conducted. Treatment decisions will not be based on this evaluation.

What are the possible benefits and risks of participating?
There are no side effects nor possible benefits for the patients when participating. The researchers will gain more knowledge about the response evaluation system.

Where is the study run from?
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
June 2023 to December 2025

Who is funding the study?
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (Netherlands)

Who is the main contact?
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Additional identifiers

Protocol serial number
IRBd23-265

Study information

Scientific Title
COMET trial: Comparison of pleural mesothelioma evaluation using volume measurements with an artificial intelligence program to the mRECIST v1.1 criteria, a prospective trial

Acronym
COMET

Study objectives
ARTIMES yields an equal or higher interobserver agreement between different radiologists compared to mRECIST v1.1.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 04/12/2023, Institutional Review Board (IRB) The Netherlands Cancer Institute (Plesmanlaan 121, Amsterdam, 1066 CX, Netherlands; +31 (0)20 51291; IRB@nki.nl), ref: IRBd23-265

Primary study design
Observational

Study design
Prospective blinded comparative non-inferiority single-centre feasibility study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pleural mesothelioma

Interventions
This is a prospective blinded comparative non-inferiority single-center feasibility study. Three radiologists will review every CT scan of adult patients with pleural mesothelioma referred to the tertiary center according to the mRECIST v1.1 and ARTIMES. Confirmation bias could occur if a radiologist assigns progressive disease (PD) following mRECIST v1.1 and is afterwards segmenting extra volume to ensure a PD for ARTIMES as well. To reduce this bias, the same CT scan needs to be reviewed for mRECIST and ARTIMES on different days with a washout of at least 4 weeks. The sequence in which both methods are used will be random. Reviewers will be blinded for their own results and for the results of the other reviewers.

Intervention Type
Other

Primary outcome(s)
The interobserver agreement among experts employing the ARTIMES criteria and the gold standard (mRECIST v1.1 criteria), measured at the end of the study using kappa

Key secondary outcome(s)
1. Time needed to measure response evaluation in minutes between the ARTIMES vs mRECIST v1.1 criteria, measured in minutes for every scan at every evaluation point
2. Time until partial response (PR) and progressive disease (PD) in days between the ARTIMES vs mRECIST v1.1 criteria, measured in days at every evaluation point
3. The response evaluation of the treating physician with the ARTIMES criteria and the mRECIST v1.1. criteria per evaluation point, compared at every evaluation point
4. The performance of the AI in segmenting pleural mesothelioma tumour volume vs the final segmentation of the reviewers, compared at every evaluation point

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Histology or cytology-proven non-resectable pleural mesothelioma
2. Age ≥18 years
3. Availability of a baseline CT thorax with contrast before the start of new systemic treatment with a slice increment of ≤3 mm on the CT scan
4. Availability of at least one follow-up scan (the lungs must be fully contained in the image)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. CT scans with lungs not fully imaged
2. No histology-proven pleural mesothelioma

Date of first enrolment
01/12/2023

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Antoni van Leeuwenhoek hospital / NKI
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX

Sponsor information

Organisation
Antoni van Leeuwenhoek Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The data will be stored for at least 20 years and as long as proven useful for scientific research.

IPD sharing plan summary
Available on request